

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number B-01								
		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-10-030		Contract Period 06/01/2010 To 05/31/2011 Base <input checked="" type="checkbox"/> Option Period Number								
Contractor TOXSERVICES LLC		Title of Work Assignment/SF Site Name								
Contractor TOXSERVICES LLC		Specify Section and paragraph of Contract SOW								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 06/15/2010 To 05/31/2011								
Comments:										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
06/01/2010 To 05/31/2011				0						
This Action:				20						
Total:				20						
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:		LOE:						
Cumulative Approved:		Cost/Fee:		LOE:						
Work Assignment Manager Name Chanya Harris _____ (Signature) _____ (Date)						Branch/Mail Code: Phone Number 919-541-1160 FAX Number:				
Project Officer Name Chanya Harris _____ (Signature) _____ (Date)						Branch/Mail Code: Phone Number: 919-541-1160 FAX Number:				
Other Agency Official Name _____ (Signature) _____ (Date)						Branch/Mail Code: Phone Number: FAX Number:				
Contracting Official Name Sandy Licis _____ (Signature) _____ (Date)						Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:				

**PERFORMANCE WORK STATEMENT
TOXSERVICES CONTRACT #EP-C-10-030
WORK ASSIGNMENT #B-01**

TITLE: Preparation of a Quality Project Plan (QAPP) for Handling Primary and Secondary Data

WORK ASSIGNMENT MANAGER:

Shirley Harrison
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Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
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Washington, DC 20460
Phone: 202/566-1107 Fax: 202/566-1140
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PERIOD OF PERFORMANCE: Work Assignment Issuance through May 31, 2011

LOE HOURS: 20 hours

PURPOSE: The purpose of this work assignment is for the contractor to develop a generic Quality Project Plan (QAPP) for handling primary and secondary data for the life of the contract (EP-C-10-030). The QAPP shall apply accordingly to each work assignment. Specific work assignments may require a supplemental QAPP, as determined by the WAM in consultation with the Quality Assurance Coordinator, or if the contractor deviates from the generic QAPP.

STATEMENT OF WORK:

The EPA has developed a Quality System to manage the quality aspects of its environmental data collection, generation, and use. The goal of the EPA Quality System is to ensure that its environmental data are of sufficient quantity and quality to support the data's intended use. The EPA Quality System requires that each EPA Office, Region, and ORD Laboratory, and Center develop and implement supporting Quality Systems.

As identified in the Office of Water Quality Management Plan, all projects that involve environmental monitoring and data collection shall include a Quality Assurance Project Plan.

Information on EPA quality assurance requirements can be found in the EPA QA web site: <http://www.epa.gov/quality/>.

Task Area 0: Work plan and monthly progress reports

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost

estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff.

If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail.

Task Area 1: Preparation of generic contract Quality Project Plan (QAPP)

1. The contractor shall develop a Quality Assurance Project Plan. The QAPP shall be in accordance with the "QAPP Requirements for Secondary Data"
2. The contractor shall submit the draft QAPP to EPA for review.
3. The contractor shall incorporate any comments or changes from EPA to QAPP.
4. The contractor shall submit final QAPP for EPA approval.

SCHEDULES / DELIVERABLES:

- | | |
|--|---------------------------|
| 1. Submittal of Draft QAPP to EPA for Review | 1 week after WP approval |
| 2. Submittal of final QAPP to EPA for Approval | 2 weeks after WP approval |

TRAVEL: No travel anticipated.

**PERFORMANCE WORK STATEMENT
TOXSERVICES CONTRACT #EP-C-07-030
WORK ASSIGNMENT # B-02**

WORK ASSIGNMENT: Regulatory Determination 3

**WORK ASSIGNMENT
MANAGER (WAM):**

Joyce Donohue
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ALTERNATE WAM

Melanie Young
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For Delivery (FEDEX or UPS) : Use Address below:

U.S. Environmental Protection Agency
OW/OST/HECD (4304-T)
EPA West-Connecting Wing, Room 5233MM
1301 Constitution Avenue, NW
Washington, DC 20460

PERIOD OF PERFORMANCE: WA Issuance through May 31, 2011

SOW TASKS: 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.1.10, 3.1.12, 3.4, 3.5

LOE HOURS: 1970 hours

BACKGROUND:

The Safe Drinking Water Act, as amended in 1996 (SDWA) requires EPA to publish every five years a list of contaminants, the Contaminant Candidate List (CCL), that are not subject to any proposed or promulgated National Primary Drinking Water Regulations (NPDWRs), are known or anticipated to occur in public water systems (PWSs), and may require regulation under SDWA. SDWA also directs EPA to determine whether to regulate at least five contaminants from the CCL every five years; this is known as the Regulatory Determination process. The Agency must publish a Maximum Contaminant Level Goal (MCLG) and promulgate an NPDWR for a contaminant if the Administrator determines that the following three statutory criteria are met:

- The contaminant may have an adverse effect on the health of persons,
- The contaminant is known to occur or there is substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern, and
- Regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

It should be noted that the Regulatory Determination Process includes notice and an opportunity for public comment but is not a rulemaking.

The third Contaminant Candidate List (CCL3) was published in October 2009. The Regulatory Determinations associated with CCL3 are due to be proposed in 2012. The Office of Science and Technology (OST) provides support to the Office of Ground Water and Drinking Water by preparing the Health Effects Support Document (HESD) for Regulatory Determination. The HESD is the source of the data for the first statutory question and provides the bench mark against which the drinking water occurrence data are compared in order to answer the second statutory question. That benchmark is termed the Health Reference Level (HRL).

Each HESD covers the properties, occurrence, toxicokinetics, toxicity, and risk characterization for an individual chemical or related grouping of chemicals. The Template for the HESD was prepared under Contract EP-C-07-021 Work Assignment (WA) 2-09. Literature searches for toxicity and toxicokinetic chapters for chemicals were also completed under that WA.

Work on the Hazard Identification (Section 7), and Dose-Response (Section 8) portions of the HESD will be completed under this work Assignment. Sections 2, 3, 4, and 5 will be imported as the products of separate Work Assignment efforts when they are completed. The Executive Summary (Section 1) and Risk Characterization (Section 9) components are prepared near the end of the Regulatory Determination Process and will be added to the WA by amendment once the chemicals for which Regulatory Determination will continue are known.

This WA includes some carryover work from WA 2-09 under Contract EP-C-07-021 as follows:

- A toxicokinetic chapter for N-Nitrosodipropylamine will be prepared under this WA. It was added to the Regulatory Determination list near the end of the prior contract. The literature search and document retrieval were completed under the prior contract but the chapter was not prepared.
- Some revisions to the draft toxicokinetic chapters from WA 2-09 will be requested through written technical directions when necessitated (e.g. when important new publications are identified or as a result of comments from the Quality Assurance review of the draft chapters).

Regulatory Determination 3 chemicals covered by this by this WA and their associated chemical managers are provided below:

1,2,3-Trichloropropane – Nancy Chiu (The IRIS Toxicological Review will be used for Sections 6, 7, and 8)
N-Nitrosodibutylamine (NDBA) - Steven Kueberuwa (202-566-0223)
N Nitrosodiethylamine (NDEA) – Steven Kueberuwa
N-Nitrosodimethylamine (NDMA) - Steven Kueberuwa
N-Nitrosodi-n-propylamine (NDPA) – Steven Kueberuwa
N-Nitrosomethylethylamine (NMEA)- Steven Kueberuwa
NNitrosopyrrolidine (NPYR) - Steven Kueberuwa
Acetochlor and its OA and OSA degradates – Ambika Bathija (202-566-1087)
Alachlor and its OA and OSA degradates – Amal Mahfouz (202-566-1114)
Metolachlor and its OA and OSA degradates – Ambika Bathija
Molybdenum – Melanie Young/Joyce Donohue (202-566-1098/2-2-250-8817)
Strontium – Amal Mahfouz
Vanadium – Nancy Chiu (202-566-1093)

If new chemicals are added to the Regulatory Determination list by the Agency Work Group they will be added to the WA by amendment.

QUALITY ASSURANCE

The tasks in this work assignment require the use of primary and/or secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP) to assure the quality of the secondary data used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1, below.

NOTE: The contractor is in the process of establishing a QAPP under this contract. Once the QAPP has been approved, the QAPP shall adhered to all work assignments under this contract

STATEMENT OF WORK

TASK 1: Work Plan and Monthly Progress Reports

Task 1 provides the funding for preparation of the WA Plan, any subsequent amendments and other activities that apply to the work plan in its entirety including the preparation of the required monthly reports and documentation for quality assurance activities.

The contractor shall prepare and submit the Work Plan in response to this work plan request. The Work Plan shall include a detailed schedule, with deliverables, a list of the key individuals who shall be involved in the technical aspects of the project and required, as well as conflict of interest and quality assurance declarations. Descriptions of the professional qualifications of personnel involved in the work assignment do not have to be subdivided by Task and can be

included in an appendix to the WA Plan. The cost estimate shall include the direct staff costs associated with the level of effort hours as well as any itemized indirect costs, but does not have to be subdivided by Task. The contractor shall prepare monthly reports for WA

Task 2: HESD Template

A template for the HESD documents was prepared under contract # EP-C-07-021 WA 2-09. Some changes to that template are likely to occur during the regulatory determination process. ToxServices will make the necessary changes to the template as they occur and make sure that any changes are incorporated into the in-process documents. The Forward will be kept up to date with regard to identifying the supporting assessments from other Offices within EPA, prior Health Advisories, or assessments by other authoritative Agencies (See Table 1). The List of applicable Agency Guidance documents and significant literature searches will also be updated as needed.

Task 3: Regulatory Determination Literature Searches

Focused follow-up literature searches for chemicals that were initially completed under Contract #EP-C-07-021 may be required. Each chemical manager will submit a description of follow-up search needs to ToxServices through the EPAWAM as needed. Assume at least one follow-up search per chemical/

The literature searches will be delivered through the EPA WAM to the Chemical Managers as they are completed. Before delivery, the search should be reviewed by the ToxServices chemical manager with designation of papers suggested for retrieval identified through highlighting of the first line for each unit of search output. The HESD chemical manager will review the search and add or subtract articles highlighted for retrieval before returning the search to the ToxServices through the EPA WAM.

The Contractor shall conduct new literature searches (author, title, source, abstract) covering pharmacokinetics/toxicokinetics; systemic-, developmental-, reproductive-, immunological-, neurological- and tumorigenic- toxicity; as well as genotoxicity of each for each new chemical that is added to Regulatory Determination.

Task 4: Regulatory Determination Document Retrieval

ToxServices shall retrieve documents selected from the literature search by the chemical managers after the chemical manager has retrieved any that are available through EPA library services. Assume retrieval for up to 5 papers/chemical with 30% requiring use of a retrieval service.

Task 5: Section 6 (Toxicokinetics) of the HESDs

The draft Section 6 for N-Nitrosodipropylamine was not prepared under the prior WA. Thus, it will be prepared under this new WA following the Template outline.

The drafts of Section 6 completed under Contract #EP-C-07-021 may need some follow-up and updating after the internal QA and as the regulatory determination work continues in the next year. Technical directions from the chemical manager issued through the EPA WAM shall be used to specify any follow-up changes to the draft chapters.

If it becomes necessary to conduct PBPK modeling for specific chemicals during the Regulatory Determination process funding will be added to this task through an amendment. If new chemicals are added to Regulatory Determination during the process they also will be added through amendment.

Task 6: Section 7 (Hazard Identification) of the HESDs

Chapter 7 of the HESD is the summary of hazard for each chemicals or group of chemicals. The nature of the studies to be included is reflected in the Template outline. The primary focus is on studies using the oral route of exposure. Thus, it is not necessary to include a detailed analysis for inhalation and dermal exposures. However, in cases where the inhalation and or dermal exposure routes are important for risk characterization, it is appropriate to include some description of the effects observed via the inhalation and/or dermal exposure routes when such data are available. Unique endpoints of toxicity can also be integrated into the outline when they are important after consultation with the chemical manager. The draft of Section 7 should be submitted to the chemical manager for review before proceeding to Task 7. After the chemical manager returns the Section with comments, the contractor shall make the requested revisions.

Task 7: Section 8 (Dose-Response Analysis) of the HESDs.

Each of the chemicals presently in the Regulatory Determination process has a current EPA assessment and/or assessments from other agencies such as ATSDR or Cal EPA or IOM (Table 1). After completion of Sections 6 and 7 of the HESD, the Contractor should meet with the chemical manager (in person or through conference call) to discuss quantification issues relative to the RfD and cancer assessment. During that discussion critical studies should be identified, and approaches to quantification considered. Following those discussions, the chemical manager shall provide written technical directions to the contractor through the EPA WAM that outline the approaches(s) that will be used for quantification and the justification for departing from an existing agency assessment.

Any chemicals with a cancer assessment that was conducted under the EPA (1986) guidelines will be reassessed under the 2005 guidelines with application of the Age Dependant Adjustment Factors (ADAF), where appropriate. In cases where revisions to the RfD are justified, they should be conducted following the guidelines from the RfD/RfC Workgroup. Each of these guidelines can be accessed from the IRIS website (<http://www.epa.gov/iris/backgrd.html>). 1,2,3 – trichloropropane will require application of the ADAFs because they are not applied in the IRIS assessment.

The draft of Section 8 will be submitted to the chemical manager for review once it is completed. After the chemical manager returns the Section with comments to the EPA WAM, the contractor shall make the requested revisions via EPA WAM.

Any new assessment will require external peer review before a final HRL can be provided to OGWDW for inclusion in Section 4 (prepared by to OGWDW). Peer Review will be accomplished under a different Contract. The HRL language for Section 4 will be prepared under this task. Funding for Post peer review revisions will be added to the WA by amendment.

Task 8 Incorporation of Sections 2, 3, 4, 5 into the HESDs

Sections 2, 3, and 5 of the HESD are being completed under a different contract vehicle. When those sections are complete they will be provided to ToxServices by the chemical manager through the EPA WAM for incorporation into the HESD template after being checked against the master template to insure consistency across chemicals.

Section 4 is prepared by the OGWDW. That chapter cannot be completed until after the monitoring data are complete and the HRL is final. Once it is provided to OST, it too will be sent to ToxServices by the EPA WAM for inclusion in the Template.

SCHEDULE AND DELIVERABLES:

Task 1 Two Weeks after receiving the Work Plan request.

Task 2: As needed.

Task 3: As needed.

Task 4: As needed.

Task 5: 4 weeks for the N-nitrosodi-n-propylamine chapter; as needed for revisions to existing draft chapters.

Task 6: Draft 8-10 weeks after receiving the Work Plan request; draft revisions 3 weeks after receiving chemical manager comments. (The effort involved will vary with the chemical.)

Task 7: Draft 4-6 weeks after the consultation with the chemical manager and agreement on the critical studies and quantification request and receipt of written technical directions from the chemical manager as sent by the EPA WAM; draft revisions 3 weeks after receiving chemical manager comments. (The effort involved will vary with the chemical.).

Task 8: 2 weeks after each Section has been provided to ToxServices by the EPA WAM

Table 1: Risk Assessments Identified by EPA for the Regulatory Determination Chemicals	
Chemical	Available Assessments
1,2,3-trichloropropane	September 30, 2009 IRIS Toxicological Review and Summary
NDMA	<p>IRIS Summary for NDMA (1987)</p> <p>OW Health Advisory for NDMA (2010)</p> <p>ATSDR Toxicological Profile (1989)</p> <p>Cal EPA Public Health goal for NDMA (2006)</p> <p>http://oehha.ca.gov/water/phg/pdf/122206NDMAphg.pdf</p> <p>WHO CICAD for NDMA (2002)</p> <p>http://www.inchem.org/documents/cicads/cicads/cicad38.htm</p> <p>WHO Drinking Water Guideline Background Document for NDMA (2008)</p> <p>http://www.who.int/water_sanitation_health/dwq/chemicals/ndma_2add_fe_b2008.pdf</p> <p>IARC Summary on NDMA, (1978)</p> <p>http://monographs.iarc.fr/ENG/Monographs/vol17/volume17.pdf</p> <p>NTP Report on Carcinogens (2005)</p> <p>http://ntp.niehs.nih.gov/ntp/roc/elevanth/profiles/s127nitr.pdf</p>
NDEA	<p>IRIS Summary for NDEA (1986)</p> <p>IARC (1972, 1978)</p> <p>http://monographs.iarc.fr/ENG/Monographs/vol1/volume1.pdf#11</p> <p>http://monographs.iarc.fr/ENG/Monographs/vol17/volume17.pdf</p> <p>NTP Report on Carcinogens (2005)</p> <p>http://ntp.niehs.nih.gov/ntp/roc/elevanth/profiles/s127nitr.pdf</p>
NDBA	<p>IRIS Summary for NDBA (1986)</p> <p>IARC Summary for NDBA (1978)</p> <p>http://monographs.iarc.fr/ENG/Monographs/vol17/volume17.pdf</p> <p>NTP Report on Carcinogens (2005)</p> <p>http://ntp.niehs.nih.gov/ntp/roc/elevanth/profiles/s125nitr.pdf</p>
NDPA	<p>IRIS Summary for NDPA (1987)</p> <p>IARC Summary for NDPA (1978)</p> <p>http://monographs.iarc.fr/ENG/Monographs/vol17/volume17.pdf</p> <p>NTP Report on Carcinogens (2005)</p> <p>http://ntp.niehs.nih.gov/ntp/roc/elevanth/profiles/s129nitr.pdf</p>
NMEA	<p>IRIS Summary for NMEA (1987)</p> <p>IARC Summary on NMEA (1978)</p> <p>http://www.inchem.org/documents/iarc/vol17/nitrosomethylethylamine.html</p>
NPYR	<p>IRIS Summary for NPYR (1986)</p> <p>IARC Summary for NPYR (1978)</p> <p>http://monographs.iarc.fr/ENG/Monographs/vol17/volume17.pdf</p> <p>NTP Report on Carcinogens (2005)</p> <p>http://ntp.niehs.nih.gov/ntp/roc/elevanth/profiles/s137nsop.pdf</p>

Table 1: Risk Assessments Identified by EPA for the Regulatory Determination Chemicals	
Chemical	Available Assessments
Acetochlor and its OA and OSA degradates	IRIS Summary for Acetochlor (1992) OPP RED and TRED (2006) for acetochlor
Alachlor and its OA and OSA degradates	IRIS Summary for Alachlor (1991) OW Criteria document for Alachlor (obtain from chemical manager) OW Health Advisory for Alachlor (1988) OPP RED for Alachlor (1998) Cal EPA Public Health Goal (1997) http://oehha.ca.gov/water/phg/pdf/alach_c.pdf WHO Drinking Water Guideline for Alachlor (1996) http://www.who.int/water_sanitation_health/dwg/chemicals/en/alachlor.pdf
Metolachlor and its OA and OSA Degradates	IRIS Summary for Metolachlor (1987,1988) OW Health Advisory for Metolachlor (1988) OPP RED (1994) and TRED (2002)for Metolachlor WHO Drinking Water Guideline for Metolchlor (1996) http://www.who.int/water_sanitation_health/dwg/chemicals/metolachlor.pdf
Molybdenum	IRIS Summary for Molybdenum (1991) OW Heath Advisory For Molybdenum (1993, draft) IOM Dietary Reference Intakes for Molybdenum (2001) UK Risk Assessment for Molybdenum (2003) http://www.food.gov.uk/multimedia/pdfs/evm_molybdenum.pdf WHO Drinking Water Guideline for Molybdenum (1996) http://www.who.int/water_sanitation_health/dwg/chemicals/molybdenum.p df
Strontium	IRIS Assessment for Strontium (1992) OW Health Advisory for Strontium (1993, draft) ATSDR Toxicological Profile for Strontium (2001)
Vanadium	Draft HESD for Vanadium – (to be provided by the chemical manager) ATSDR Toxicological Review for Vanadium (2009 draft) IOM Dietary Reference Intakes for Vanadium (2001) UK Risk Assessment Vanadium (2003) http://www.food.gov.uk/multimedia/pdfs/evm_vanadium.pdf
IRIS dates are verification dates from the on-line IRIS Summaries www.epa.gov/iris OPP Website http://www.epa.gov/pesticides/reregistration/status.htm	

<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> </div> <div> United States Environmental Protection Agency Washington, DC 20460 </div> </div> <div style="text-align: center; margin-top: 10px;"> <h2 style="margin: 0;">Work Assignment</h2> </div>		Work Assignment Number B-02								
<div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Other </div> <div> <input checked="" type="checkbox"/> Amendment Number: <div style="text-align: right;">000001</div> </div> </div>										
Contract Number EP-C-10-030	Contract Period 06/01/2010 To 05/31/2013 Base <input checked="" type="checkbox"/> Option Period Number	Title of Work Assignment/SF Site Name Regulatory Determination								
Contractor TOXSERVICES LLC		Specify Section and paragraph of Contract SOW see PWS								
Purpose: <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div> <input type="checkbox"/> Work Assignment <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Work Plan Approval </div> <div> <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Incremental Funding </div> </div>		Period of Performance From 07/27/2010 To 05/31/2011								
Comments:										
<div style="display: flex; justify-content: space-between; align-items: center;"> <input type="checkbox"/> Superfund </div> <div style="text-align: center; margin-top: 10px;"> Accounting and Appropriations Data </div> <div style="text-align: right; margin-top: 10px;"> <input checked="" type="checkbox"/> Non-Superfund </div>										
<div style="display: flex; justify-content: space-between; align-items: center;"> <div> SFO (Max 2) <div style="border: 1px solid black; width: 30px; height: 20px; display: flex; align-items: center; justify-content: center; margin-top: 5px;"> 1 </div> </div> <div> Note: To report additional accounting and appropriations data use EPA Form 1900-69A. </div> </div>										
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1										
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Authorized Work Assignment Ceiling										
<div style="display: flex; justify-content: space-between;"> <div> Contract Period: 06/01/2010 To 05/31/2013 </div> <div> Cost/Fee: _____ </div> <div> LOE: _____ </div> </div>										
This Action: _____										
Total: _____										
Work Plan / Cost Estimate Approvals										
<div style="display: flex; justify-content: space-between;"> <div> Contractor WP Dated: _____ </div> <div> Cost/Fee: _____ </div> <div> LOE: _____ </div> </div>										
<div style="display: flex; justify-content: space-between;"> <div> Cumulative Approved: _____ </div> <div> Cost/Fee: _____ </div> <div> LOE: _____ </div> </div>										
Work Assignment Manager Name Joyce Donohue <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number 202-566-1098 FAX Number: _____			
Project Officer Name Chanya Harris <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 919-541-1160 FAX Number: _____			
Other Agency Official Name _____ <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: _____ FAX Number: _____			
Contracting Official Name Sandra Stargardt-Licis <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 513-487-2006 FAX Number: _____			

**PERFORMANCE WORK STATEMENT
TOXSERVICES CONTRACT #EP-C-07-021
WORK ASSIGNMENT # B-02 Amendment 1**

WORK ASSIGNMENT: Regulatory Determination 3

**WORK ASSIGNMENT
MANAGER (WAM):**

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ALTERNATE WAM

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For Delivery (FEDEX or UPS)

Use Address below:
U.S. Environmental Protection Agency
OW/OST/HECD (4304-T)
EPA West-Connecting Wing, Room 5233MM
1301 Constitution Avenue, NW
Washington, DC 20460

PERIOD OF PERFORMANCE: June 1, 2010 through May 31, 2011

SOW TASKS: 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.1.10, 3.1.12, 3.4, 3.5

TOTAL LEVEL OF EFFORT (LOE) HOURS: 1970 Hours

The Purpose of this amendment is to increase the number of references retrieved per chemical in Task 4 from 5 to 45 with one-third requiring use of a retrieval service (i.e. payment for the paper).

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number B-02								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000002								
Contract Number EP-C-10-030		Contract Period 06/01/2010 To 05/31/2013 Base <input checked="" type="checkbox"/> Option Period Number								
Contractor TOXSERVICES LLC		Title of Work Assignment/SF Site Name								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 07/27/2010 To 05/31/2013								
Comments:										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
06/01/2010 To 05/31/2013										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:		LOE:						
Cumulative Approved:		Cost/Fee:		LOE:						
Work Assignment Manager Name Joyce Donohue						Branch/Mail Code:				
_____ (Signature)						_____ (Date)				
Project Officer Name Chanya Harris						Phone Number 202-566-1098				
_____ (Signature)						_____ (Date)				
Other Agency Official Name						FAX Number:				
_____ (Signature)						_____ (Date)				
Contracting Official Name Sandra Stargardt-Licis						Branch/Mail Code:				
_____ (Signature)						_____ (Date)				
						Phone Number 513-487-2006				
						FAX Number:				

**PERFORMANCE WORK STATEMENT
TOXSERVICES CONTRACT #EP-C-07-030
WORK ASSIGNMENT # B-02 Amd 2**

WORK ASSIGNMENT: Regulatory Determination 3

**WORK ASSIGNMENT
MANAGER (WAM):**

Joyce Donohue
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division (MC 4304T)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
Phone #: 202-566-1098 Fax #: 202-566-1140
E-mail- donohue.joyce@epa.gov

ALTERNATE WAM:

Melanie Young
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division (MC 4304T)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
Phone #: 202-250-8817 Fax #: 202-566-1140
E-mail- young.melanie@epa.gov

For Delivery (FEDEX or UPS)

Use Address below:
U.S. Environmental Protection Agency
OW/OST/HECD (4304-T)
EPA West-Connecting Wing, Room 5233MM
1301 Constitution Avenue, NW
Washington, DC 20460

PERIOD OF PERFORMANCE: June 1, 2010 through May 31, 2011

SOW TASKS: 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.1.10, 3.1.12, 3.4, 3.5

LOE HOURS: 0 Hours

PURPOSE OF AMENDMENT: The purpose of this amendment is to add another chemical to the work assignment (sodium chlorate) and changes the chemicals manager for nitroso-di-n-propylamine to Melanie Ekstrand for the duration of her rotation with the Health and Ecological Criteria Division (November 7, 2010 to March 7, 2011). After Melissa's rotations ends, Steven Kueberuwa will return to being the chemical manager.

No LOE hours or new Tasks are included with the amendment. Additional amendments will be required as more of the FY-2011 budget becomes available to HECD and the direction of the Regulatory Determination is refined.

**PERFORMANCE WORK STATEMENT
TOXSERVICES CONTRACT #EP-C-07-021
WORK ASSIGNMENT # B-02 Amendment 3**

WORK ASSIGNMENT: **Regulatory Determination 3**

WORK ASSIGNMENT

MANAGER (WAM): Joyce Donohue

Office of Water, Office of Science and Technology
Health and Ecological Criteria Division (MC 4304T)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
Phone #: 202-566-1098 Fax #: 202-566-1140
E-mail- donohue.joyce@epa.gov

For Delivery (FEDEX or UPS)

Use Address below:

U.S. Environmental Protection Agency
OW/OST/HECD (4304-T)
EPA West-Connecting Wing, Room 5233MM
1301 Constitution Avenue, NW
Washington, DC 20460

PERIOD OF PERFORMANCE: June 1, 2010 through May 31, 2011

SOW TASKS: 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.1.10, 3.1.12, 3.4, 3.5

LOE: 850 Hours

BACKGROUND.

Work Assignment B-02 was initiated in August 2010 using the FY-2010 Health and Ecological Criteria Division (HECD) funding available for work on Health Effects Support Documents for Regulatory Determination 3. The contractor has accomplished the retrieval of references for Sections 7 and 8 of the Health Effects Support Documents (12), delivered the drafts for the hazard identification chapters (13) to the chemical managers and completed some dose-response modeling for 6 chemicals.

This amendment adds additional level of effort hours and funds to the work assignment to support the preparation of section 8 of the HESD (Task 7) for each of the chemicals included in the work assignment as well as Nitrosodiphenylamine as an additional chemical. This work assignment is being funded incrementally as funding is received through continuing resolutions. In addition this amendment expands the description of Task 8 to include corrections and editorial revisions to chapters 2, 3, and 5 as problems are identified during the Quality Assurance review for those chapters. The original description for this Task only covered insertion of the chapters [prepared under a different contract] into the HESD template.

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number B-03 <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-10-030	Contract Period 06/01/2010 To 05/31/2011 Base <input checked="" type="checkbox"/> Option Period Number	Title of Work Assignment/SF Site Name								
Contractor TOXSERVICES LLC		Specify Section and paragraph of Contract SOW Health Effects Screening Approach for Po								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 08/18/2010 To 05/31/2011								
Comments:										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
06/01/2010 To 05/31/2011										
This Action:				0						
				0						
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:		LOE:						
Cumulative Approved:		Cost/Fee:		LOE:						
Work Assignment Manager Name Octavia Conerly _____ (Signature) _____ (Date)						Branch/Mail Code: Phone Number 202-566-1094 FAX Number:				
Project Officer Name Chanya Harris _____ (Signature) _____ (Date)						Branch/Mail Code: Phone Number: 919-541-1160 FAX Number:				
Other Agency Official Name _____ (Signature) _____ (Date)						Branch/Mail Code: Phone Number: FAX Number:				
Contracting Official Name Sandy Licis _____ (Signature) _____ (Date)						Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:				

**PERFORMANCE STATEMENT OF WORK
TOXSERVICES CONTRACT #EP-C-10-030
WORK ASSIGNMENT #B-03**

Title: Health Effects Screening Approach for Pharmaceuticals – National Academy of Sciences Follow-up

EPA Work Assignment Manager

Octavia Conerly
U.S. Environmental Protection Agency
Office of Science and Technology, Office of Water
Health and Ecological Criteria Division
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EPA East Connecting Wing Room 5233PP
Washington, DC 20460
Telephone #: 202-566-1094 FAX #: 202-566-1140
Email: conerly.octavia@epa.gov

LOE: 350 hours

Period of Performance: Work Assignment Issuance through May 31, 2011

BACKGROUND

Pharmaceuticals have been discovered in this nation's ambient waters, wastewater, and drinking water at very low levels. EPA has a strategy to respond to this issue, including improving science through research, improving public understanding, identifying partnership opportunities, and taking regulatory action when appropriate. There are thousands of pharmaceuticals on the market today and still more that are approved daily. This creates a challenge for the Agency since most of these compounds do not have environmentally relevant data or publically available health effects data. Therefore, as a part of our strategy, EPA is examining ways to screen a broad range of pharmaceuticals based upon health benchmark indicators, structure similarities, class of compound, etc.

In December 2008, EPA sponsored a National Academy of Sciences (NAS) workshop where experts were brought together to provide input on possible prioritization and risk assessment approaches for pharmaceuticals. This work assignment is follow-up work resulting from the workshop.

In a previous work assignment (WORK ASSIGNMENT #2-08, contract EP-C-07-021), a draft paper was developed. This work assignment is a continuation of the previous assignment and provides a vehicle to further develop and refine a process for screening pharmaceuticals based on health benchmark indicators and applying this process to several groups of pharmaceuticals using health effects data from FDA. This process should allow EPA to screen out compounds.

In addition, a short paper discussing the full scope of regulatory challenges encountered during the Agency's attempt to address the pharmaceuticals in water issue will be drafted (EPA will finalize internally).

A separate concurrent assignment (not part of this WA) is being conducted to develop a scheme for grouping pharmaceuticals based upon occurrence in drinking water, surface water and biosolids (e.g., classified by structural similarities or drug classes, etc). Upon completion of both approaches, EPA will synthesize the approaches. The contractor shall (see Task #6) implement the synthesized approach on specific classes of compounds and issue a final report. This report will characterize whether the synthesized approach was successful and report results of the screening.

QUALITY ASSURANCE

The tasks in this work assignment require the use of primary and/or secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP), which has been provided by the contractor, will assure the quality of the secondary data used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports provided as specified.

STATEMENT OF WORK

Objective 1: Support EPA's research program by developing a process that can be used to screen and prioritize pharmaceuticals found/have the potential to occur in water and biosolids.

Objective 2: Support EPA's research program by developing a process that can potentially be used to screen contaminants other than pharmaceuticals.

SCOPE OF WORK AND DELIVERABLES BY TASK

Task 1. The contractor shall develop a work plan addressing the tasks of the work assignment and submit it to the EPA WAM.

Work plan to EPA WAM

2 weeks following the receipt of statement of work

Task 2. The contractor shall continue to refine the draft report on proposed processes/approaches that can be used to screen a broad range of pharmaceuticals based on health benchmark indicators such as relative potency factors, thresholds of toxicological concern, the use of marker or sentinel compounds to serve as toxic surrogates for an entire chemical class of compounds or other classification schemes. The draft report should include the proposed approaches for screening, strengths and weaknesses of each approach, and a recommendation as to how the process might be used to screen for pharmaceuticals. Concurrently, the contractor shall develop a short discussion paper (5 – 8 pages single spaced) focusing on regulatory challenges encountered during the Agency's efforts to implement the four pronged strategy for

addressing contaminants of emerging concern such as pharmaceuticals in water. The contractor shall submit the draft reports to the EPA WAM for comment.

Regulatory challenges draft	2 weeks following work plan approval
Refine draft screening report	6 weeks following work plan approval

Task 3. Following receipt of comments from the EPA WAM, the contractor shall schedule a conference call to discuss the EPA WAM's comments on the draft screening report. After discussions with the EPA WAM via conference call, the contractor shall incorporate the EPA WAM's comments.

Conference call w/ EPA WAM	Within 2 working days of receipt of EPA WAM comments
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Task 4. Once comments have been incorporated, the contractor shall submit the revised draft report to the EPA WAM for review.

Revised draft report	4 weeks following conference call with EPA WAM
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Task 5. Upon receipt of comments from the EPA WAM, the contractor shall incorporate the comments and submit a final draft to the EPA WAM for final review.

Final draft report	3 weeks following receipt of EPA WAM comments
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Task 6. The contractor shall finalize the report based on final review comments from the EPA WAM and then submit a final document to the EPA WAM.

Finalization of report	4 weeks after receipt of final WAM comments
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Task 7. The EPA WAM shall provide specific groupings of pharmaceuticals to the contractor to conduct a screening assessment based on health effects by using the approach identified. The contractor shall develop a draft report of the results of the implementation of the approach and should also include a discussion of the application history of the proposed process or similar processes in regulatory settings and submit it to the EPA WAM for review and comment.

Draft report of results for implementation of approach	8 weeks following receipt of groupings from EPA WAM
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Task 8. The contractor shall arrange for a conference call to discuss the draft report with the EPA WAM.

Conference call w/EPA WAM	Within 2 working days of receipt of EPA WAM comments
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EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number B-03								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001								
Contract Number EP-C-10-030		Contract Period 06/01/2010 To 05/31/2011 Base <input checked="" type="checkbox"/> Option Period Number								
Contractor TOXSERVICES LLC		Title of Work Assignment/SF Site Name Health Effects-Pharmaceuticals								
Contractor TOXSERVICES LLC		Specify Section and paragraph of Contract SOW								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 06/01/2010 To 05/31/2011								
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund <div style="text-align: center;">Accounting and Appropriations Data</div> <input checked="" type="checkbox"/> Non-Superfund </div>										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
06/01/2010 To 05/31/2011				0						
This Action:				300						
Total:				300						
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:		LOE:				
Cumulative Approved:				Cost/Fee:		LOE:				
Work Assignment Manager Name Octavia Conerly <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number 202-566-1094 FAX Number:				
Project Officer Name Shirley Harrison <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:				
Other Agency Official Name <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: FAX Number:				
Contracting Official Name Sandra Stargardt-Licis <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:				

**PERFORMANCE STATEMENT OF WORK
TOXSERVICES CONTRACT #EP-C-10-030
WORK ASSIGNMENT #B-03 AMD #1**

Title: Health Effects Screening Approach for Pharmaceuticals – National Academy of Sciences Follow-up

EPA Work Assignment Manager

Octavia Conerly
U.S. Environmental Protection Agency
Office of Science and Technology, Office of Water
Health and Ecological Criteria Division
1200 Pennsylvania Ave., NW MC 4304T
EPA East Connecting Wing Room 5233PP
Washington, DC 20460
Telephone #: 202-566-1094 FAX #: 202-566-1140
Email: conerly.octavia@epa.gov

LOE: 300 hours

Period of Performance: Work Assignment Issuance through May 31, 2011

PURPOSE OF AMENDMENT

The purpose of this amendment is to add hours, dollars and additional tasks (9-13) to this work assignment.

QUALITY ASSURANCE: same as the original work assignment

Workplan: The contractor shall develop a work plan addressing the tasks of the work assignment and submit to the EPA WAM

Work plan to EPA WAM

2 weeks following the receipt of statement
of work

ADDITIONAL TASKS

Task 9

The contractor shall revise the data summary for the Selective Serotonin Reuptake Inhibitors (SSRIs) and complete data summaries for three other classes of drugs (macrolides, progesterones and statins) and submit the summaries to the EPA WAM for comments.

Submission of draft summaries for comment

3 weeks following work plan
approval

Task 10

Upon receipt of comments from the EPA WAM, the contractor shall incorporate the comments and submit a revised draft to the EPA WAM for review and additional comment.

Submission of revised draft summaries 2 weeks following receipt of EPA WAM review comments

Task 11

The contractor shall continue work to develop a draft report of the screening and grouping approach for pharmaceuticals that includes the implementation results of the approach and should also include a discussion of the application history of the proposed process or similar processes in regulatory settings and submit it to the EPA WAM for review and comment.

Submission of draft report 4 weeks following completion of Task 10

Task 12

Upon receipt of comments from the EPA WAM, the contractor shall incorporate the comments and submit a revised draft to the EPA WAM for review.

Submission of revised draft report 3 weeks following receipt of EPA WAM comments

Task 13

Upon receipt of comments from the EPA WAM, the contractor shall incorporate the comments and submit a revised final draft to the EPA WAM for review.

Submission of revised final draft 1 week following receipt of EPA WAM comments

The contractor shall await further technical direction from the EPA WAM on the additional tasks (9-13). The EPA WAM shall provide a copy of TD to the PO/CO

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number B-04			
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:			
Contract Number EP-C-10-030			Contract Period 06/01/2010 To 05/31/2011 Base <input checked="" type="checkbox"/> Option Period Number			Title of Work Assignment/SF Site Name Perchlorate Health Document			
Contractor TOXSERVICES LLC				Specify Section and paragraph of Contract SOW 2.0, 3.1, 3.3, 3.4, 3.5, 3.6.					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/01/2010 To 05/31/2011			
Comments:									
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div>									
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars) (Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1									
2									
3									
4									
5									
Authorized Work Assignment Ceiling									
Contract Period:		Cost/Fee:		LOE:					
06/01/2010 To 05/31/2011				0					
This Action:				225					
Total:				225					
Work Plan / Cost Estimate Approvals									
Contractor W/P Dated:				Cost/Fee:		LOE:			
Cumulative Approved:				Cost/Fee:		LOE:			
Work Assignment Manager Name Melanie Young <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number 202-250-8817 FAX Number:			
Project Officer Name Shirley Harrison <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:			
Other Agency Official Name Shirley Harrison <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:			
Contracting Official Name Sandra Stargardt-Licis <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:			

**PERFORMANCE WORK STATEMENT
TOXSERVICES CONTRACT #EP-C-10-030
WORK ASSIGNMENT # B-04**

TITLE: Perchlorate Health Effects Support Document (HESD)

WORK ASSIGNMENT

MANAGER:

Melanie Young
Mail Code 4304T, Room #5231YY
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
United States Environmental Protection Agency (USEPA)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Telephone #: 202-250-8817 FAX #: 202-566-1140

PERIOD OF PERFORMANCE: Work Assignment Issuance through May 31, 2011

SOW TASKS: 2.1 - 2.3, 2.5, 2.7 - 2.9, 3.1.1 - 3.1.12, 3.3.1, 3.4, 3.5, 3.6.1, 3.6.2.

LOE: 225 hours

BACKGROUND:

The mission of the United States Environmental Protection Agency's (EPA) Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of pollutants (e.g., chemicals and pathogens) in media such as surface water, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, health advisories, maximum contaminant level goals, and limits for pollutants in various water media. This work assignment directly supports the Health and Ecological Criteria Division's (HECD) mission to produce and publish scientifically sound, usable, and implementable methods, guidance, and criteria that may be utilized to protect human health in drinking water and human health in ambient water and sediment.

A Health Effects Support Document (HESD) for the chemical perchlorate is being prepared to support a newly proposed positive regulation for perchlorate in drinking water. U.S. EPA's regulatory determination for perchlorate in accordance with the Safe Drinking Water Act (SDWA) was published in the Federal Register (*FR Vol. 76, No. 29, p. 7762*) on February 11, 2011. EPA has determined that perchlorate meets SDWA's criteria for regulating a contaminant. Specifically, EPA has determined that perchlorate may have an adverse effect on the health of persons, that perchlorate is known to occur or there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern, and that in the sole judgment of the Administrator, regulation of perchlorate in drinking water systems presents a meaningful opportunity for health risk reduction for persons served by public water systems. Therefore, EPA has initiated the process of developing and establishing a national primary drinking water regulation (NPDWR) for perchlorate.

QUALITY ASSURANCE

The tasks in this work assignment require only the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP) to assure the quality of the secondary data used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1, below. The tasks in this Work Assignment (WA) do not require primary data from environmental measurement and/or generation of laboratory data.

PERFORMANCE WORK STATEMENT:

The principal focus of this work assignment is to revise and update a HESD for the drinking water contaminant perchlorate, and to provide supplementary scientific health effects analyses in support of this document. Specifically, this work assignment requires the critical re-evaluation, qualitative, and quantitative analyses of all human (as well as any animal) data relevant to potentially adverse human health effects of perchlorate that have been published in the scientific literature primarily from the start of the year 2004. U.S. EPA's objective is to develop an all-encompassing weight-of-evidence approach for developing the final perchlorate HESD, and for subsequently developing the Maximum Contaminant Level Goal (MCLG) and Maximum Contaminant Level (MCL) for perchlorate, in support of the newly proposed positive EPA drinking water regulatory determination for perchlorate.

The EPA WAM will be the point of contact for all contractual matters related to this Work Assignment, as well as for all of the technical and scientific aspects of each of the Tasks. Technical directions may be issued by the WAM, the Project Officer (PO), and/or the Contracting Officer (CO), to clarify or add specification to the Task descriptions provided under the Scope of Work. Any technical direction to the contractor by the EPA WAM, the PO and CO shall receive a copy within five days.

The contractor shall update and complete the final version of the perchlorate HESD, using the HESD template provided by the EPA WAM. The perchlorate HESD document will be updated and completed based on a previously prepared draft HESD for perchlorate, and also based upon information obtained from recent full literature searches. The contractor shall be responsible for updating and completing all sections of the perchlorate HESD (see HESD template provided). This perchlorate HESD shall be prepared in accordance with all Agency guidelines as described in the FOREWORD of the HESD template, and also according to any specific technical direction provided by the EPA WAM.

The contractor shall submit drafts (using Microsoft Office 2007) of all deliverables to the EPA WAM for review prior to submission of the final product. These drafts will clearly specify the methods, procedures, considerations, assumptions, relevant citations, data sources, and data that support any conclusions and recommendations. All drafts and final products shall be completely free of any typographical and/or grammatical errors. The contractor shall incorporate all of the EPA WAM's technical directions and comments (and peer review comments, where applicable) into all final deliverables.

TASKS

Task 1. Work Plan and Monthly Progress Reports

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, a staffing plan, level of effort (LOE) computed by specific task and cost estimate for each task, the key assumptions on which staffing plan and budget are based, the professional qualifications (including resumes) of any proposed staff to complete the specified work assignment tasks, and a project specific supplement (PS-QAPP). The scientific disciplines needed for revising and updating this perchlorate HESD, and for providing supplementary scientific health effects analyses in support of this HESD are listed as follows: academic training in epidemiology and research toxicology. The contractor's estimated LOE may differ from that estimated by EPA in the work assignment but the overall LOE shall not exceed the total LOE specified in the work assignment submittal. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All "P" levels, hours, and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The work plan shall also provide an analysis of the existing and projected constraints, and the feasibility of accomplishing the project's purpose. A table that summarizes the financial reporting for each task shall be included with the monthly progress reports. In addition, the monthly progress report shall provide greater detail of the progress on each task and its financial status in sufficient detail for the EPA WAM to assess progress relative to the task expenditures.

In addition, the contractor shall prepare a PS-QAPP to ensure the quality of secondary data used to complete these tasks. In the final report, the contractor shall summarize the QA measures and processes used and incorporated in the work assignment.

A separate tracking monthly summary must be prepared for the WAM using the following format:

WA # and Task#	Task Description	Initial budget	Current month Cost	Projected Cost following month	Balance remaining
WA B-XX Task 1	Work Plan and Monthly Reports	\$7,000.00	\$350.00	\$350.00	\$6,650.00
WA B-XX Task 2	Health Effects Support Document (HESD) for Perchlorate	\$7,000.00	\$350.00	\$350.00	\$6,650.00
Total		\$14,000.00	\$700.00	\$700.00	\$13,300.00

Task 2. Revised Preliminary Draft Health Effects Support Document (HESD) for Perchlorate

The contractor shall revise and prepare all sections of the preliminary final draft HESD for perchlorate, using the EPA 2010 HESD template provided. The contractor shall prepare this draft HESD as specified in technical direction from the EPA WAM; this technical direction will include the EPA 2010 HESD EPA template and the current draft perchlorate HESD. The contractor shall provide the preliminary final draft product to the EPA WAM.

Task 3. Evaluation/Summary of New Literature Relevant to Perchlorate Health Effects

The contractor shall evaluate all known literature/data published since 2004 and develop a summary table of relevant information from this evaluation (e.g., study population, study design, exposure/outcome variables, exposure/outcome assessment, health outcome statistics, etc.). The contractor shall prepare the contents of this summary table as specified by specific format technical direction from the EPA WAM; this technical direction will include the literature to review, evaluate, and incorporate. The contractor shall provide the draft summary table to the EPA WAM.

Task 4. Evaluation of U.S. States' Programmatic Bases for Perchlorate Regulation

The contractor shall gather and tabulate all other (50) U.S. states' and territories', as available, currently existing or proposed bases and quantitative derivation for regulation of perchlorate in drinking water or groundwater. The contractor shall prepare the contents of this summary table as specified by specific format technical direction from the EPA WAM. The contractor shall provide the draft summary table to the EPA WAM.

Task 5. Develop and Draft a Cumulative Exposure Chapter Describing Other Thyroid Inhibitors for the Health Effects Support Document (HESD) for Perchlorate

The contractor shall develop and prepare a draft cumulative exposure and potential cumulative risk chapter describing the current state of scientific knowledge of other thyroid inhibitors/goitrogens (e.g., nitrate, thiocyanate). This information will be based in part on existing text describing some additional chemicals that affect the thyroid in the current draft HESD. The contractor shall prepare the contents of this new draft chapter as specified by technical direction from the EPA WAM; this technical direction will include the literature to review, evaluate, and incorporate. The contractor shall provide the draft chapter to the EPA WAM.

Task 6. Develop and Draft Dose/Exposure-Response Arrays across Human Health and Animal Studies of the Health/Biological Effects of Perchlorate Exposure

The contractor shall develop and prepare draft graphical arrays of dose/exposure-response characteristics of human health and animal studies describing the adverse biological/health effects of perchlorate exposure. The contractor shall prepare the contents of this task as specified by technical direction from the EPA WAM; this technical direction will include the literature to review, evaluate, and incorporate. The contractor shall provide this draft product to the EPA WAM.

Task 7. Draft Final Health Effects Support Document (HESD) for Perchlorate

The contractor shall revise and finalize all sections of the preliminary final draft HESD for perchlorate from Task 2. The contractor shall prepare the final draft HESD as specified in technical direction from the EPA WAM; this technical direction will include the preliminary final draft perchlorate HESD specifically provided by the EPA WAM at the start of this task, any new the literature to review, evaluate, and incorporate, and any additional information developed from Task #3, Task #4, Task #5, and Task #6 as specified by the EPAWAM. The contractor

shall provide this final product to the EPA WAM.

SCHEDULE AND DELIVERABLES:

- Task 1.** **Fifteen (15) days** after receipt of the work assignment (**Work Plan**).
- Task 2.** **One (1) week** after approval of the work plan by the EPA WAM, and provision of the EPA-conducted literature search results by the EPA WAM (**Revised Preliminary Draft HESD**).
- Task 3.** **One (1) week** after receipt of technical direction from the EPA WAM (**Summary Health Effects Literature Evaluation Tabulation**).
- Task 4.** **One (1) week** after receipt of technical direction from the EPA WAM (**U.S. States'/Territories' Existing/Proposed Perchlorate Regulations Summary Tabulation**).
- Task 5.** **One (1) week** after receipt of technical direction from the EPA WAM (**Draft HESD Chapter for Cumulative Exposure to Other Goitrogens**).
- Task 6.** **One (1) week** after receipt of technical direction from the EPA WAM (**Perchlorate Health/Biological Effects Dose/Exposure-Response Studies Graphical Arrays**).
- Task 7.** **One (1) week** after receipt of technical direction from the EPA WAM (**Draft Final HESD**).

TRAVEL: No travel is anticipated under this work assignment. Any travel directly chargeable to this work assignment must be submitted in advance and approved by the Project Officer and EPA WAM.

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number 1-02 <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-10-030		Contract Period 06/01/2010 To 05/31/2012 Base Option Period Number 1								
Contractor TOXSERVICES LLC		Title of Work Assignment/SF Site Name Regulatory Determination 3								
Specify Section and paragraph of Contract SOW see PWS										
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 06/01/2010 To 05/31/2011								
Comments:										
<input type="checkbox"/> Superfund		Accounting and Appropriations Data								
		<input checked="" type="checkbox"/> Non-Superfund								
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE: 0						
06/01/2010 To 05/31/2012										
This Action:				1,560						
				1,560						
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:				LOE:		
Cumulative Approved:				Cost/Fee:				LOE:		
Work Assignment Manager Name Shirley Harrison <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number 202-566-1107 FAX Number:			
Project Officer Name Shirley Harrison <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name Sandra Stargardt-Licis <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div><i>Sandra Licis</i> (Signature)</div> <div>5/24/11 (Date)</div> </div>							Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:			

PERFORMANCE WORK STATEMENT
TECHNICAL AND REGULATORY SUPPORT FOR THE DEVELOPMENT
OF CRITERIA/LIMITS FOR WATER MEDIA (TOXICOLOGY EMPHASIS)

1.0 INTRODUCTION

1.1 Background

The mission of the United States Environmental Protection Agency's Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of pollutants (e.g., chemicals and pathogens) in media such as ground and surface waters, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, health advisories, maximum contaminate level goals, and limits for pollutants in various water media.

1.2 Purpose of Contract

The purpose of this contract is to provide technical and regulatory support services to the Health and Ecological Criteria Division (HECD) in OST for the development of human health criteria, health advisories, maximum contaminant level goals, and pollutant limits. This support includes activities such as conducting literature search and literature reviews; conducting hazard, exposure and risk assessments; performing statistical analyses; evaluating pollutants selected for review by the United States Environmental Protection Agency (EPA); assessing the potential impact of criteria on sensitive populations; preparing criteria documents; preparing health advisories, preparing technical guidance documents, preparing technical support documents for regulatory requirements; preparing the index of references for proposed and final regulations; summarizing comments on proposed regulations; and arranging and conducting workshops.

2.0 GENERAL TASKS

2.1 The Contractor shall furnish all facilities, materials, equipment, and necessary professional, technical, and support personnel in support of the effort delineated below. The initial submission of all documents shall be in draft form for EPA review and comment. Required revisions will be provided to the Contractor by EPA for incorporation into a final document.

2.2 The Contractor shall possess or have access to appropriate equipment/software to perform mathematical modeling and statistical analyses in support of criteria development.

2.3 The Contractor shall develop documents and data bases using EPA standard software (e.g. Word, Excel, Lotus Notes and Power Point), as specified in a work assignment. Software documentation shall be accessible to the EPA Work Assignment Manager (WAM) and other persons authorized by the EPA Project Officer (PO).

2.4 The Contractor shall possess or have access to a laboratory that can analyze pollutants (e.g., organic pollutants using gas chromatography/mass spectrometry, metals using atomic absorption) in water media (e.g., wastewater, surface water, drinking water, and sewage sludge), as specified in a work assignment.

2.5 The Contractor shall prepare a Quality Assurance Project Plan (QAPP) for work assignments that require environmental measurements or the use of secondary data.

2.6 The Contractor shall handle all Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) confidential business information (CBI) in accordance with the clauses in Section H of this contract. The Contractor shall also comply with the security requirements found in the FIFRA

Information Security Manual and the TSCA Confidential Business Information Security Manual.

2.7 The Contractor shall provide information that will be used by EPA for quick responses and analyses of options, issues, and policy decisions as they relate to the tasks in this Performance Work Statement (PWS). Quick responses are those that require completion in one to seven days, or as specified in a work assignment. EPA will review results of all Contractor analyses, and make a final determination with regard to program objectives and policy decisions.

2.8 The Contractor shall comply with the requirements for studies and rulemaking records contained in authorities such as the Administrative Procedures Act, the Paperwork Reduction Act, the Clean Water Act, OMB Circular A-130 for management of Federal Information Resources, and the Federal Rules of Appellate Procedure (Rules 16 and 17, 28 U.S.C. Appendix).

2.9 The Contractor shall perform the specific tasks in the PWS in accordance with the appropriate EPA risk assessment guidance and science policy guidance (e.g., guidance on the development of a risk reference dose for a non-carcinogen), as indicated in a work assignment.

3.0 SPECIFIC TASKS

3.1 Human Health

3.1.1 The Contractor shall prepare summaries of peer-reviewed literature on toxicity, clinical and epidemiological endpoints, as specified in a work assignment. Each summary shall discuss the test protocol (e.g., endpoints measured; test animal; the number, sex, and species of animals in the control group and dosing groups; the method, frequency, and duration of dosing; and sacrifice and pathology data), and shall evaluate the test protocol with respect to EPA published test requirements under TSCA and FIFRA. Similarly, for epidemiological studies, the Contractor shall evaluate the protocol, type of study (e.g., case-controlled, community, prospective, or retro prospective), analyses, and conclusions according to Bradford-Hill criteria.

3.1.2 The Contractor shall prepare screening analyses that display and compare all available data for a pollutant, and build on the summaries in subsection 3.1.1. If required by the work assignment, these analyses shall be presented as electronic data bases.

The Contractor shall be able to develop figures, tables or other graphics to display the array of available data for a pollutant building on the summaries in subsection 3.1.1. The requested data arrays may be requested to assist in risk communication, facilitate the dose-response assessments and improve the transparency of health effects support documents.

The Contractor shall collect data, prepare screening analyses and participate in the development of screening methodologies for chemical contaminants that will be useful in the development of future Contaminate Candidate Lists (CCLs), prioritizing resources, and in identifying emerging contaminants.

3.1.3 The Contractor shall be familiar with the EPA Toxics Release Inventory data base, and other Federal and private release and exposure data bases. The Contractor shall document the methodology, assumptions, and rationales used in the analyses. EPA will make the final decision concerning a finding based on the appropriate technical information and Agency policy.

3.1.4 The Contractor shall prepare, evaluate, and revise health effects documents. These documents provide information on the criteria that protect human health from exposure to a chemical in water media. The Contractor shall document the

methodology, assumptions, and rationales used for this task. EPA will make the final decision concerning a health effects document based on the appropriate technical information and Agency policy.

A health effects document for a chemical shall address, as specified in a work assignment: (1) physical and chemical properties of the chemical; (2) occurrence in water and other media, (3) environmental fate and transport; (4) toxicokinetics; (5) human exposure to the chemical; (6) health effects in animals and humans; (7) mechanisms of toxicity; (8) magnitude of carcinogenic and non- carcinogenic effects including the relative source contribution ; (9) risk characterization, and (10) any other areas set forth in the work assignment. Examples of documents the Contractor shall prepare include the documents that support CCL Regulatory Determinations, documents for six-year review of regulations which may be considered for revision if new data suggests revision, drinking water regulations and development of human health criteria for ambient water. Standard EPA formats for these documents will be provided by the EPA PO/WAM. During the development of a health effects document, the Contractor shall conduct literature reviews to augment the file of references provided by the EPA WAM with other references.

3.1.5 The Contractor shall prepare, evaluate, and revise health advisories for chemicals. A health advisory provides information that public health officials use to help determine control priorities for pollutants in water media (e.g., drinking water, surface water, and sediments) as well as general information for the public. The Contractor shall document the methodology, assumptions, and rationale used to prepare, evaluate, and revise a health advisory. EPA will make the final decision concerning a health advisory based on the appropriate technical information and Agency policy.

A health advisory for a chemical shall address: (1) general information and properties of the chemical; (2) occurrence and environmental fate and transport; (3) pharmacokinetics; (4) health effects in animals and humans; (5) quantification for carcinogenic and non-carcinogenic effects, (6) treatment technologies; (7) analytical methods; (8) risk characterization; and (9) any other areas set forth in the work assignment. During the development of a health advisory, the Contractor shall conduct literature reviews to augment the file of references provided by the EPA WAM with other references.

3.1.6 The Contractor shall provide technical support during the preparation, evaluation, and revision of hazard, exposure, or risk assessment/characterization techniques or methodologies for human health protection. This includes, among other things, providing technical support during the development of methodologies used to develop human health criteria for various water media (e.g., surface water and drinking water). The Contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning a technique or methodology based on the appropriate technical information and Agency policy.

3.1.7 The Contractor shall provide on a rapid response basis analyses of human health risk assessment guidelines, results of human health risk assessments, and treatment technology practices and procedures. This includes, among other things, analysis of the impact of criteria on sensitive populations, and analyses of dose response data, pharmacokinetics data, exposure data, and bioaccumulation data.

3.1.8 The Contractor shall prepare, evaluate, and revise technical guidance documents for chemicals. These documents provide information on the principles for criteria development (e.g., minimum data requirements and exposure assumptions). The Contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning a technical guidance document based on the appropriate technical information and Agency policy.

3.1.9 The Contractor shall evaluate "raw" data generated from a toxicity study. The raw data will be provided by the EPA WAM. The evaluation shall include a complete description of the protocol used to gather the data; analyses of effects observed including tabulation of all observations and pathology for individual test animals; evaluation of biological significance of endpoints according to EPA published guidelines or other technical documents; statistical analyses of significance of observations; and conclusions as to existence of treatment-related effects and their implications for human health. If required by a work assignment, the Contractor shall engage and convene a panel of experts to conduct a review of tissue preparations and slides from the test to characterize and classify lesions observed.

3.1.10 The Contractor shall conduct Monte Carlo or similar statistical uncertainty analyses of toxicity or epidemiological endpoint incidence data or exposure data, as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance.

The Contractor shall model the dose response data from cancer and noncancer studies using benchmark dose, categorical regression or other similar methodologies developed by the Agency as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance for the methodology used.

3.1.11 The Contractor shall provide analyses of food consumption patterns and associated intake of pollutants for the U.S. population. These shall include frequency and amount of specific foods consumed by sex, age, and geographical locations. Data to be analyzed shall include data from Federal data collection efforts, State collection efforts, and other available studies. Similarly, the Contractor shall provide analyses of exposure data from the Center for Disease Control National Health and Nutrition Examination Survey (NHANES) data base and the EPA National Human Exposure Assessment Survey data base.

3.1.12 All of the above tasks and deliverables shall be completed in accordance with EPA published guidelines (e.g., carcinogenic risk assessment guidelines, reproductive risk assessment guidelines, developmental risk assessment guidelines, neurotoxicity guidelines, exposure assessment guidelines, risk characterization policy guidelines, benchmark dose guidelines or Monte Carlo guidelines).

3.2 Sewage Sludge

3.2.1 The Contractor shall provide technical support during the preparation, evaluation, and revision of procedures for selecting pollutants-of-concern in sewage sludge that is used or disposed of, and shall provide technical support during the evaluation of those pollutants. The Contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning the procedure used to select pollutants-of-concern and the evaluation of those pollutants based on the appropriate technical information and Agency policy.

3.2.2 The Contractor shall conduct exposure pathway risk assessments for pollutants in sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. The pathways evaluated for each use or disposal practice shall be the pathways evaluated for each practice when the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503) were developed, and other pathways specified in a work assignment. Results of the risk assessments will be used by EPA to develop limits for pollutants in the sewage sludge.

3.2.3 The Contractor shall prepare, evaluate, and revise technical support documents for a standard for the use or disposal of sewage sludge. These documents

contain the rationales for the requirements (i.e., general requirements; pollutant limits; management practices; operational standards; and frequency of monitoring, record keeping, and reporting requirements) in a sewage sludge use or disposal standard (see 40 CFR Part 503).

The Contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning a technical support document based on the appropriate technical information and Agency policy.

3.3 Statistics Support

3.3.1 The Contractor shall have statistical analyses capabilities to perform analyses of environmental data for toxicological pollutants to derive descriptive or interpretative statistics.

3.3.2 The Contractor shall conduct laboratory/field studies to support the development of water quality criteria, maximum contaminant level goals, sewage sludge pollutant limits, and other program requirements, as specified in a work assignment.

3.4 Administrative Record Support

The Contractor shall provide data and documentation to be used by EPA in the analysis of technical issues and options for proposed and final regulations, as specified in a work assignment. Deliverables under this task include data summaries, technical reports, option papers, issue papers, and public and confidential records and files. The Contractor shall describe and document the data gathering activities; display, characterize, and interpret the data and information collected; obtain copies of any references used; and describe all methodologies used. Written reports and corresponding records and files shall be prepared and organized, indexed, and cross-referenced in an administrative record for a proposed or final regulation so that the analyses and conclusions can be reproduced based on the information in the administrative record for a proposed or final regulation.

3.5 Rule making support

The Contractor shall index and summarize public comments on proposed regulations. Using information provided by EPA (i.e., typically public comments submitted in response to a proposed regulation and information collection requests), the Contractor shall prepare an index of issues in the information provided by EPA, and cross reference those issues to the public comments. For technical issues assigned by the EPA WAM, the Contractor shall, based on knowledge of the appropriate rule making, prepare draft technical responses to the issues in the public comments including all relevant citations to the administrative record. EPA will review the draft technical responses, and prepare the final responses to the comments.

3.6 Preparation of outreach materials

3.6.1 The Contractor shall develop outreach materials in support of the tasks in this PWS. These materials include brochures, presentation boards, slide shows, fact sheets, pamphlets, posters, videos, INTERNET layouts, and models. The materials shall be developed for use in media events (e.g., press releases). In addition, the Contractor shall provide materials for distribution at presentations. All materials shall be provided in accordance with the limitations set for in the Section H clause titled "PRINTING (EPAAR 1552.208-70)." The Contractor shall provide a draft of all materials for approval by the EPA WAM, and shall prepare the final materials based on the EPA WAM's comments on the draft materials. For print products, the Contractor shall provide a camera-ready copy and a disk copy in a disk format that enables the material to be loaded onto the INTERNET. This task only shall be done in direct support of the technical requirements in

this PWS.

3.6.2 The Contractor shall provide, when included in a work assignment, a complete and accurate translation of foreign language articles cited in a criteria document, a health advisory, or a technical guidance document. Translations shall be performed by experienced scientific translators well-versed in chemical, toxicological, statistical, biomedical, or epidemiological terminology. The Contractor shall insure that there are no terminology or language usage ambiguities that make interpretation and analysis of the findings difficult. No translations shall be made without the written approval of the Project Officer.

3.7 Arranging and conducting workshops

The Contractor shall provide support in arranging workshops, conferences, training sessions, and public meetings, and obtaining appropriate individuals to address various issues. Meeting support shall be limited in scope, and shall cover only those meetings required to address the requirements in this PWS. The Contractor shall arrange travel only in accordance with the authority and limitations in the Section H clause titled "APPROVAL OF CONTRACTOR TRAVEL" (i.e., use of contract funds to reimburse travel is strictly limited to logistical support for speakers, scientists, and experts who contribute directly to the requirements of a task in this PWS). The Contractor shall support EPA by: (1) providing information for meeting agendas, including typing the agendas; (2) preparing drafts of technical information for use in preparing briefing materials; (3) identifying and inviting speakers and experts to participate in a workshop; (4) arranging for meeting space when Government space is not available; (5) arranging for the appropriate audio-visual equipment; (6) providing advance announcements, registration support, visual aid preparation, logistical support, case study preparation, interactive and role-playing activity development; and (7) preparing the minutes of the meeting, including the meeting results, for approval by the EPA PO/WAM.